## (19) World Intellectual Property Organization International Bureau





(43) International Publication Date 24 March 2005 (24.03.2005)

**PCT** 

## (10) International Publication Number WO 2005/026116 A1

- (51) International Patent Classification<sup>7</sup>: C07D : A61K 31/40, A61P 3/06
- C07D 207/34,
- (21) International Application Number:

PCT/IB2004/002919

(22) International Filing Date:

6 September 2004 (06.09.2004)

(25) Filing Language:

English

(26) Publication Language:

English

- (30) Priority Data: 60/503,592
- 17 September 2003 (17.09.2003) US
- (71) Applicant (for all designated States except US): WARNER-LAMBERT COMPANY LLC [US/US]; 201 Tabor Road, Morris Plains, NJ 07950 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): CAMPETA, Anthony, Michael [US/US]; Pfizer Global Research & Development, Easter Point Road, Groton, CT 06340 (US). KRZYZANIAK, Joseph, Francis [US/US]; Pfizer Global, Research and Development, Eastern Point Road, Groton, CT 06340 (US). LEONARD, Jason, Albert [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US).

- (74) Agent: FULLER, Grover, F., Jr.; Pfizer Inc., 201 Tabor Road, Morris Plains, 07950 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

## Published:

with international search report

Groton, CT 06340 (US). **LEONARD**, Jason, Albert For two-letter codes and other abbreviations, refer to the "Guid-lus" [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CRYSTALLINE FORMS OF 'R-(R\*,R\*)]-2-(4-FLUOROPHENYL)-BETA,DELTA-DIHYDROXY-5-(1-METHYLETHYL)-3-PHENYL-4-'(PHENYLAMINO)CARBONYL!-1H-PYRROLE-1-HEPTANOIC ACID

(57) Abstract: Novel crystalline forms of [R-(R\*,R\*)]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-l-heptanoic acid (atorvastatin free acid) designated Form A and Form B, characterized by their X-ray powder diffraction pattern and solid-state NMR spectra are described, as well as methods for the preparation and pharmaceutical composition of the same, which are useful as agents for treating hyperlipidemia, hypercholesterolemia, osteoporosis, benign prostatic hyperplasia, and Alzheimer's Disease, and for preparing salts of atorvastatin.

